

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION

^NOxyNEO[®]
Oxycodone Hydrochloride Controlled Release Tablets

Read this carefully before you start taking OxyNEO and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about OxyNEO.

Serious Warnings and Precautions

- Even if you take OxyNEO as prescribed you are at risk for opioid addiction, abuse, and misuse that can lead to overdose and death. To understand your risk of opioid addiction, abuse, and misuse you should speak to your prescriber (e.g., doctor).
- Life-threatening breathing problems can happen while taking OxyNEO, especially if not taken as directed. Babies are at risk of life-threatening breathing problems if their mothers take opioids while pregnant or nursing.
- Never give anyone your OxyNEO. They could die from taking it. If a person has not been prescribed OxyNEO, taking even one dose can cause a fatal overdose. This is especially true for children.
- If you took OxyNEO while you were pregnant, whether for short or long periods of time or in small or large doses, your baby can suffer life-threatening withdrawal symptoms after birth. This can occur in the days after birth and for up to 4 weeks after delivery. If your baby has any of the following symptoms:
 - as changes in their breathing (such as weak, difficult or fast breathing)
 - is unusually difficult to comfort
 - has tremors (shakiness)
 - has increased stools, sneezing, yawning, vomiting, or feverSeek immediate medical help for your baby.

Taking OxyNEO with other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.

What is OxyNEO used for?

OxyNEO is used for the long-term management of pain, when:

- the pain is severe enough to require daily, around-the-clock pain medication
- the doctor determines that other treatment options are not able to effectively manage your pain.

OxyNEO is NOT used (“as needed”) to treat pain that you only have once in a while.

How does OxyNEO work?

OxyNEO is an oral controlled release tablet that slowly releases oxycodone hydrochloride over a 12-hour period.

OxyNEO contains oxycodone which is a pain medication belonging to the class of medicines known as opioids which includes codeine, fentanyl and morphine. It relieves pain by acting on specific nerve cells of the spinal cord and brain.

What are the ingredients in OxyNEO?

Medicinal ingredients: oxycodone hydrochloride

Non-medicinal ingredients: butylated hydroxytoluene, hypromellose, magnesium stearate, polyethylene glycol, polyethylene oxide, silicon dioxide, titanium dioxide.

In addition, the tablet coatings contain the following:

10 mg: hydroxypropylcellulose

15 mg: iron oxide

20 mg, 30 mg, 40 mg and 60 mg: polysorbate 80 and iron oxide

80 mg: hydroxypropylcellulose, iron oxide and FD&C Blue No. 2

OxyNEO comes in the following dosage forms:

Controlled Release Tablets: 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg and 80 mg.

Do not use OxyNEO if:

- your doctor did not prescribe it for you
- you are allergic to oxycodone hydrochloride, other opioids, or any of the other ingredients of OxyNEO (see What are the ingredients in OxyNEO?)
- you have mild or short-term pain that can be controlled by the occasional use of pain medications, including those available without a prescription
- you have difficulty in swallowing or have been diagnosed with narrowing of the esophagus
- you have severe asthma, trouble breathing or other lung problems
- you have a condition where the small bowel does not work properly (paralytic ileus) or you have severe pain in your abdomen
- you have a head injury
- you are at risk for seizures
- you suffer from alcoholism
- you are taking, or have taken within the past 2 weeks, a monoamine oxidase inhibitor (MOI) medication (such as phenelzine sulphate, tranylcypromine sulphate, moclobemide or selegiline)
- you are pregnant or plan to become pregnant, or you are in labour
- you are breastfeeding
- you are under 18 years of age
- you are going to have, or recently had, a planned surgery

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take OxyNEO. Talk about any health conditions or problems you may have, including if you:

- have a history of illicit or prescription drug or alcohol abuse
- have severe kidney, liver or lung disease
- have heart disease
- have low blood pressure
- have a history of sleep apnea

- have past or current depression
- have problems with your thyroid, adrenal or prostate gland
- suffer from chronic or severe constipation
- have, or had in the past hallucinations or other severe mental problems
- suffer from migraines
- are planning to become pregnant

Other warnings you should know about:

Opioid dependence and addiction

There are important differences between physical dependence and addiction. It is important that you talk to your doctor if you have questions or concerns about abuse, addiction or physical dependence

Pregnancy, nursing, labour and delivery

Do not use OxyNEO while pregnant, nursing, during labour or delivery. Opioids can be transferred to your baby through breast milk, or while still in the womb. OxyNEO can then cause life-threatening breathing problems in your unborn baby or nursing infant.

If you are pregnant and are taking OxyNEO, it is important that you don't stop taking your medication all of a sudden. If you do, it can cause a miscarriage or a still-birth. Your doctor will monitor and guide you on how to slowly stop taking OxyNEO. This may help avoid serious harm to your unborn baby.

Driving and using machines

Before you do tasks which may require special attention, you should wait until you know how you react to OxyNEO. OxyNEO can cause:

- drowsiness
- dizziness
- light headedness

This can usually occur after you take your first dose and when dose is increased.

Disorder of the adrenal gland

You may develop a disorder of the adrenal gland called adrenal insufficiency. This means that your adrenal gland is not making enough certain hormones. You may experience symptoms such as:

- nausea, vomiting
- feeling tired, weak or dizzy
- decreased appetite

You may be more likely to have problems with your adrenal gland if you have been taking opioids for longer than one month. Your doctor may do tests, give you another medication, and slowly take you off OxyNEO.

Serotonin Syndrome

OxyNEO can cause serotonin syndrome, a rare but potentially life-threatening condition. It can cause serious changes in how your brain, muscles and digestive system work. You may develop serotonin syndrome if you take OxyNEO with certain anti-depressants or migraine medications.

Serotonin syndrome symptoms include:

- fever, sweating, shivering, diarrhea, nausea, vomiting;
- muscle shakes, jerks, twitches or stiffness, overactive reflexes, loss of coordination;
- fast heartbeat, changes in blood pressure;
- confusion, agitation, restlessness, hallucinations, mood changes, unconsciousness, and coma.

Sexual Function/Reproduction

Long term use of opioids may lead to a decrease in sex hormone levels. It may also lead to low libido (desire to have sex), erectile dysfunction or being infertile.

Sleep Apnea

Opioids can cause a problem called sleep apnea (stopping breathing from time to time while sleeping). Tell your doctor if you have a history of sleep apnea or if anyone notices that you stop breathing from time to time while sleeping.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with OxyNEO:

- alcohol, including prescription and non-prescription medications containing alcohol. **Do not** drink alcohol while taking OxyNEO. It can lead to:
 - drowsiness
 - unusually slow or weak breathing
 - serious side effects
 - a fatal overdose
- other sedative drugs which may enhance the drowsiness caused by OxyNEO
- other opioid analgesics (for pain)
- general anesthetics (used during surgery)
- drugs used to help you sleep or to reduce anxiety
- antidepressants (for depression and mood disorders). Do not take OxyNEO with monoamine oxidase (MAO) inhibitors or if you have taken MAO inhibitors in the last 14 days before treatment with OxyNEO
- drugs used to treat serious mental or emotional disorders, such as schizophrenia
- antihistamines (for allergies)
- anti-emetics (for prevention of vomiting)
- drugs used to treat muscle spasms and back pain
- warfarin and other coumarin anticoagulants (for prevention/treatment of blood clots)
- some heart medication (beta blockers)
- anti-retroviral,azole-anti-fungal and macrolide-antibiotic drugs
- grapefruit juice
- St. John's Wort

How to take OxyNEO:

OxyNEO tablets are designed to work properly over 12 hours when swallowed whole.

Swallow whole. Do not cut, break, chew, dissolve or crush OxyNEO tablets before swallowing since this can lead to the release and absorption of an excessive dose of oxycodone which can seriously harm you.

Do not take the 60 mg or 80 mg strength or a single dose of 40 mg or more of OxyNEO unless you are “opioid tolerant”. Your doctor will tell you when you are “opioid tolerant” to a certain dose of OxyNEO.

OxyNEO can be taken with or without food.

In order to reduce the possibility of choking on the tablets or difficulty swallowing:

- **You must take OxyNEO tablets one at a time;**
- **Do not pre-soak, lick or otherwise wet the tablet prior to placing it in your mouth;**
- **Take each tablet with enough water to ensure complete swallowing immediately after placing it in your mouth.**

If you experience difficulty swallowing or pain after taking OxyNEO, seek immediate medical attention, as you may require medical assistance to remove the tablet. You should not take OxyNEO if you have difficulty swallowing or have been diagnosed with narrowing of the esophagus.

Do not administer OxyNEO via nasogastric, gastric or other feeding tubes as it may cause obstruction of feeding tubes.

OxyNEO is not recommended for rectal administration.

Usual Dose:

Dosage is individualized. Be sure to follow your doctor’s dosing instructions exactly. Do not increase or decrease your dose without consulting your doctor. Taking higher doses can lead to more side effects and a greater chance of overdose.

Review your pain regularly with your doctor to determine if you still need OxyNEO. Be sure to use OxyNEO only for the condition for which it was prescribed.

Should your pain increase or any other complaint develop as a result of taking OxyNEO, tell your doctor immediately.

Stopping your Medication:

You should not stop taking OxyNEO all at once if you have been taking it for more than a few days.

Your doctor will monitor and guide you on how to slowly stop taking OxyNEO. You should do it slowly to avoid uncomfortable symptoms such as having:

- body aches
- diarrhea
- goosebumps
- loss of appetite
- nausea
- feeling nervous or restless
- runny nose
- sneezing
- tremors or shivering
- stomach cramps
- rapid heart rate (tachycardia)

- having trouble with sleeping
- an unusual increase in sweating
- heart palpitations
- an unexplained fever
- weakness
- yawning

By reducing or stopping your opioid treatment, your body will become less used to opioids. If you start treatment again, you will need to start at the lowest dose. You may overdose if you restart at the last dose you took before you slowly stopped taking OxyNEO.

Refilling Prescriptions for OxyNEO:

A new written prescription is required from your doctor each time you need more OxyNEO. Therefore, it is important that you contact your doctor before your current supply runs out.

Only obtain prescriptions for this medicine from the doctor in charge of your treatment. Do not seek prescriptions from other doctors unless you switch to another doctor for your pain management.

Overdose:

If you think you have taken too much OxyNEO, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Signs of overdose may include:

- unusually slow or weak breathing
- dizziness
- confusion
- extreme drowsiness

Missed Dose:

It is important that you do not miss any doses. If you miss a dose, take your next dose at your usual time. You should always try to get back on track with your regular dosing schedule (e.g., 8 o'clock in the morning and 8 o'clock in the evening). If you miss several doses in a row, talk to your doctor before restarting your medication.

What are possible side effects from using OxyNEO?

These are not all the possible side effects you may feel when taking OxyNEO. If you experience any side effects not listed here, contact your healthcare professional.

Side effects may include:

- constipation
- dizziness
- drowsiness
- dry mouth
- headache
- itching
- weakness, uncoordinated muscle movement
- nausea, and/or vomiting, or poor appetite

- sweating
- insomnia
- abdominal pain
- fever
- diarrhea
- indigestion
- tremor
- abnormal dreams or thoughts
- anxiety
- confusion
- depression
- nervousness
- rash
- difficulty breathing
- low sex drive, impotence (erectile dysfunction), infertility

Talk with your doctor or pharmacist about ways to prevent constipation when you start using OxyNEO.

If nausea and vomiting become troublesome during prolonged therapy with OxyNEO, talk to your doctor or pharmacist.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
RARE			
Overdose: hallucinations, confusion, inability to walk normally, slow or weak breathing, extreme sleepiness, sedation, or dizziness, floppy muscles/low muscle tone, cold and clammy skin.			✓
Respiratory Depression: slow, shallow or weak breathing.			✓
Allergic Reaction: rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing.			✓
Bowel Blockage (impaction): abdominal pain, severe constipation, nausea.			✓
Withdrawal: nausea, vomiting, diarrhea, anxiety, shivering, cold and clammy skin, body aches, loss of appetite, sweating.		✓	
Fast, Slow or Irregular Heartbeat: heart palpitations.		✓	

Low Blood Pressure: dizziness, fainting, light-headedness.	✓		
Serotonin syndrome: agitation or restlessness, loss of muscle control or muscle twitching, tremor, diarrhea			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- **Keep unused or expired OxyNEO in a secure place to prevent theft, misuse or accidental exposure.**
- Store at room temperature (15° - 30°C). Keep in a dry place.
- **Keep OxyNEO under lock, out of sight and reach of children and pets.**
- **Never take medicine in front of small children as they will want to copy you. Accidental ingestion by a child is dangerous and may result in death. If a child accidentally takes OxyNEO, get emergency help right away.**

Disposal:

OxyNEO should never be thrown into household trash, where children and pets may find it. It should be returned to a pharmacy for proper disposal.

If you want more information about OxyNEO:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<http://hc-sc.gc.ca/index-eng.php>); the manufacturer’s website <http://www.purdue.ca>, or by calling 1-800-387-4501.

This leaflet was prepared by Purdue Pharma

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